NMCP COVID-19 Literature Report #20: Tuesday, 09 June 2020

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Disclaimer: I am not a medical professional. This document is current as of the date noted above. While I make every effort to find and summarize available data, things are changing rapidly, with new research and potentially conflicting literature published daily. Best practice and evidence are constantly shifting during this international public health crisis.

Reports are biweekly, planned for Tuesdays and Fridays.

Statistics

Global 7,155,952 confirmed cases and 407,302 deaths in 188 countries/regions

United States* top 5 states by cases (Virginia is ranked 12th)

	TOTAL	NY	NJ	CA	IL	MA
Confirmed Cases	1,963,828	378,799	164,497	134,029	128,415	103,626
Tested	20,615,303	2,555,896	975,089	2,431,190	1,059,597	657,269
Recovered	NA	67,687	27,941	NA	NA	NA
Deaths	111,139	30,417	12,214	4,660	5,924	7,353

^{*}see census.gov for current US Population data; NA: not all data available

JHU CSSE as of 1100 EDT 09 June 2020

Navy (Department of Defense)

	TOTAL	MIL	CIV DEP		CTR	
Cases	627	427	86	50	64	
Hospitalized	9	3	4	0	2	
Recovered	2,786	2,180	350	145	111	
Deaths	12	1	8	0	3	
Cumulative*	3,435	2,608	444	195	178	

^{*}cumulative total = active + recovered + deaths

DOD dated 08 June 2020

Virginia	Total	Chesapeake	Hampton	Newport News	Norfolk	Portsmouth	Suffolk	Virginia Beach
Cases	51,738	605	228	323	596	351	325	815
Hospitalized	5,203	97	35	41	73	48	53	104
Deaths	1,496	15	4	10	7	11	34	27

<u>VA DOH</u> as of 1100 EDT 09 June 2020

Pediatric Inflammatory Multisystem Syndrome

Two studies—one based in the UK, the other based in New York City—published yesterday in JAMA further define the clinical and laboratory characteristics of children with the Kawasaki-like illness associated with COVID-19. The findings, per JAMA:

"This case series included 58 hospitalized children, a subset of whom required intensive care, and met definitional criteria for pediatric inflammatory multisystem syndrome temporally associated with severe acute respiratory syndrome coronavirus 2 (PIMS-TS), including fever, inflammation, and organ dysfunction. Of these children, all had fever and nonspecific symptoms, such as abdominal pain (31 [53%]), rash (30 [52%]), and conjunctival injection (26 [45%]); 29 (50%) developed shock and required inotropic support or fluid resuscitation; 13 (22%) met diagnostic criteria for Kawasaki disease; and 8 (14%) had coronary artery dilatation or aneurysms. Some clinical and laboratory characteristics had important differences compared with Kawasaki disease, Kawasaki disease shock syndrome, and toxic shock syndrome." (JAMA [UK])

"This study describes 17 previously healthy children and adolescents who developed an inflammatory phenotype related to COVID-19. Features overlapped with, but were distinct from, those of KD and TSS. The observed pattern of cytokine expression suggests an interferon signaling component, along with IL-6 and IL-10 production, seen in KD5 and acute pulmonary COVID-19 infection. The lack of elevated TNF- α or IL-13 levels may differ from acute pulmonary COVID infections.6 The occurrence of abnormal cardiac findings suggests the need for long-term surveillance. Limitations include the small number of patients, short follow-up period, and the inability to establish causality." (JAMA [NYC])

Hydroxychloroquine (HCQ) in COVID-19

Preliminary data from the UK-based RECOVERY study, a randomized control trial looking at HCQ in COVID-19 patients, released on Friday indicates no survival benefit (RECOVERY). According to a statement from the study's leaders, "there was no significant difference in 28-day mortality with HCQ versus usual care—and in fact trended toward increased risk of death with the active drug (25.7% for HCQ vs 23.5% for usual care, HR 1.11, 95% CI 0.98-1.26, P=0.10)" (MedPage).

Fallout from the Surgisphere COVID studies, including one that focused on HCQ, continues after both papers were retracted last week (<u>STAT</u> [retract]). The University of Utah terminated the appointment of the researcher involved (<u>STAT</u> [researcher]). The HCQ retraction issue means long-term consequences for medicine and research, beyond the impact on COVID-19 patients:

"Scientists say the affair raises serious questions about the way researchers and journals evaluate the data underlying papers that they publish, and may complicate the effort to trial drugs during the coronavirus pandemic.

'This whole event is catastrophic — it is problematic for the journals involved, it is problematic for the integrity of science, it is problematic for medicine, and it is problematic for the notion of clinical trials and evidence generation,' says Ian Kerridge, a bioethicist at the University of Sydney, Australia." (Nature)

A review of evidence on chloroquine and hydroxychloroquine concludes "that even if chloroquine and hydroxychloroquine are effective in COVID-19, the beneficial effects will be small" (CEBM).

For more context on the Surgisphere saga, see NMCP COVID-19 lit report #19 (SharePoint).

Summaries from Other Sources

<u>CEBM</u>: Are there risk factors and preventative interventions for acute respiratory distress syndrome (ARDS) in COVID-19? (08 June 2020)

"Seventeen studies were included in this rapid review, with older age, diabetes, certain blood tests and African American ethnicity amongst the most evidenced risk factors for ARDS. Assessments of risk associated with other comorbidities, symptoms or exposure to medications pre-admission were more inconsistent.

This evidence base should be treated with caution. Most of the studies failed to adjust for key confounders, which is of particular concern to older age, where many comorbidities are known to be more prevalent. This, combined with generally small sample sizes, leaves the results open to significant risk of bias.

Several factors may affect the generalisability of the results of these studies. In particular, the definition of COVID-19 cases varied across studies and whilst several studies used the Berlin or WHO interim guidance definitions of ARDS, others were not explicit.

In short, we found a lack of robust data regarding risk factors or prevention of COVID-19 ARDS and identified an urgent need for high quality research in this area."

<u>CEBM</u>: Thrombosis in COVID-19: clinical outcomes, biochemical and pathological changes, and treatments (04 June 2020)

"The best current strategies for confronting large vessel thrombosis in COVID-19 are prophylaxis with low-molecular-weight heparin and treatment with full-dose low-molecular-weight heparin with monitoring of anti-Factor Xa. There are no strong hypotheses regarding the pathogenesis of the coagulant effect of COVID-19 to guide therapy. Until the results of

masked randomized controlled trials are available, treatments directed against components of putative pathogenic pathways, such as interleukin and complement, should be regarded as experimental."

Selected Primary Literature

Recent—published in peer-reviewed journals within the last 7 days of report's date

<u>JAMA</u>: Association Between Mode of Delivery Among Pregnant Women With COVID-19 and Maternal and Neonatal Outcomes in Spain (08 June 2020)

"In this cohort of pregnant women in Spain, severe adverse maternal outcomes occurred in 11% (9/82), 4 of whom presented with severe and 5 with mild COVID-19 symptoms.

Among patients with mild symptoms at presentation, all patients with a vaginal birth had excellent outcomes. In contrast, 13.5% of women undergoing cesarean delivery had severe maternal outcomes and 21.6% had clinical deterioration. Women undergoing cesarean delivery may have been at higher risk of adverse outcomes, but after adjusting for confounding factors, cesarean birth remained independently associated with an increased risk of clinical deterioration. The physiological stress induced by surgery is known to increase postpartum maternal complications. Cesarean delivery was also associated with an increased risk of NICU admission."

<u>JAMA</u>: Admissions to Veterans Affairs Hospitals for Emergency Conditions During the COVID-19 Pandemic (05 June 2020)

"Between March 11 and April 21, 2020, 42% fewer patients were admitted to VA inpatient facilities compared with the preceding 6 weeks, including for conditions generally requiring emergency treatment. The percentage decrease in admissions for conditions generally requiring emergency treatment was greater or similar in magnitude to the decrease in admissions overall and is unlikely to be attributable to declines in elective surgeries or disease incidence related to reduced stress or lower exposure to other pathogens or pollution. Rather, many patients may be avoiding hospitals to minimize risk of SARS-CoV-2 infection."

<u>JAMA</u>: Caring for Women Who Are Planning a Pregnancy, Pregnant, or Postpartum During the COVID-19 Pandemic (05 June 2020)

"Recommendations:

 Place a mask on the patient on presentation and isolate in a single-person room with the door closed. Airborne isolation rooms should be used for aerosolizing procedures (ACOG, CDC, SMFM, SOAP).

- Consider separating patients with COVID-19 in one area of the obstetric unit and using a designated team of trained clinicians in these areas (SMFM, SOAP).
- Weigh benefits and risks of magnesium sulfate for fetal neuroprotection or for preeclampsia/intrapartum seizure prophylaxis given potential maternal respiratory depression (SMFM, SOAP).
- Consider adjusting antenatal corticosteroid use for fetal maturation, given the risk of worsening patient outcomes with corticosteroid use in patients with COVID-19 (eg, offer antenatal steroids for patients <34 weeks' gestation, weigh risks and benefits and individualize decisions for ≥34 weeks' gestation) (ACOG, SMFM, SOAP).
- Consider early epidural analgesia to mitigate the risks associated with general anesthesia in the setting of an urgent cesarean delivery (SMFM, SOAP).
- Do not alter delivery timing or mode (eg, cesarean delivery, operative vaginal delivery) due to patients' COVID-19 infection status. However, for women with COVID-19 in the third trimester, it may be reasonable to attempt to postpone delivery to decrease risk of neonatal transmission (ACOG).
- Consider temporary separation of mothers with confirmed COVID-19 from their newborns (ACOG, AAP, CDC).
- Determination of whether to temporarily separate a mother with known or suspected COVID-19 should be made on a case-by-case basis, using shared decisionmaking (ACOG, CDC).
- If temporary separation is chosen, mothers who intend to breastfeed should practice hand and breast hygiene and express their milk. Expressed milk can be fed to the newborn by a healthy caregiver (ACOG, AAP, CDC, SMFM, SOAP).
- If separation is not chosen, use other measures to reduce risk of infection, such as physical barriers and face mask use by the mother (AAP, CDC).
- Mothers who choose to feed at the breast should wear a face mask and practice hand and breast hygiene before each feeding (AAP, ACOG, CDC, SMFM, SOAP).
- Newborns born to mothers with confirmed COVID-19 at the time of delivery should be considered to have suspected COVID-19 and be isolated from healthy newborns (AAP, ACOG, CDC).
- Newborns born to mothers with confirmed or suspected COVID-19 at the time of delivery should be tested 24 hours after birth for SARS-CoV-2 and, if negative, again at approximately 48 hours if testing capacity is available (AAP, CDC)."

<u>JAMA Intern Med</u>: Early Intervention of Palliative Care in the Emergency Department During the COVID-19 Pandemic (05 June 2020)

"During the novel coronavirus disease 2019 (COVID-19) pandemic, it is particularly critical to ensure that life-sustaining treatment (LST) such as intubation and resource-intensive cardiopulmonary resuscitation (CPR) are aligned with a patient's goals and values, and to avoid LSTs in patients with a poor prognosis that are unlikely to be beneficial, but have a

high risk of causing additional suffering.1 The high volume and acuity of COVID-19 patients makes it extremely challenging for emergency department (ED) clinicians to take adequate time to clarify goals of care (GOC). We implemented an ED-based COVID-19 palliative care response team focused on providing high-quality GOC conversations in time-critical situations. We examined the clinical characteristics and outcomes of patients who received this intervention....

The most important finding in this study was, after palliative care intervention in the ED, most patients and their surrogates opted to forgo mechanical ventilation and/or CPR, and that tendency further increased on discharge. We believe timely GOC conversations by the palliative care team helped avoid unwanted LSTs for patients with a poor prognosis. Study limitations include potentially limited generalizability given the retrospective design at a single institution. Also, palliative care consultation was initiated by ED clinicians, which may have led to selection bias, though a high rate of altered GOC after intervention suggests significant, unaddressed need in the outlying population."

<u>JAMA Netw Open</u>: Thromboelastographic Results and Hypercoagulability Syndrome in Patients With Coronavirus Disease 2019 Who Are Critically III (05 June 2020)

"Severe acute respiratory syndrome coronavirus 2 (SAR-CoV-2) is responsible for the coronavirus disease 2019 (COVID-19) pandemic that has caused approximately 300 000 deaths globally. Disseminated intravascular coagulopathy and other COVID-19—associated coagulopathies occur among patients with severe SARS-CoV-2 infections.1 Potentially lethal hypercoagulability is an unusual, poorly defined COVID-19—associated coagulopathy presentation.2,3 We found that more than half of patients admitted to the intensive care unit (ICU) of Baylor St Luke's Medical Center developed clinically significant thromboses that were associated with hypercoagulable thromboelastographic (TEG) parameters alone....

Our finding of INR, partial thromboplastin time, and platelet levels within or close to reference ranges but elevated fibrinogen and dimerized plasmin fragment D levels reflect a complex inflammatory and hematologic profile distinct from the disseminated intravascular coagulopathy associated with COVID-19. In this context, TEG may be critical in accurately identifying patients at increased thrombosis risk and thereby avoiding unnecessary anticoagulation in patients with low thrombosis risk. Specifically, a hypercoagulable innate TEG MA yielded 100% sensitivity and 100% negative predictive value for the occurrence of multiple thromboses."

MMWR: COVID-19 Monitoring and Response Among U.S. Air Force Basic Military Trainees — Texas, March—April 2020 (05 June 2020; posted 02 June 2020 as early release)

"What is added by this report?

Nonpharmaceutical interventions (NPI) introduced among 10,579 basic trainees at Joint Base San Antonio-Lackland limited COVID-19 incidence to five cases (47 per 100,000 persons), three of which were in persons who were contacts of the first patient.

What are the implications for public health practice?

Despite documented outbreaks of COVID-19 in congregate settings, implementation of NPIs, including screening, testing, administrative measures, quarantine, isolation, and source control, can limit transmission of symptomatic COVID-19 and ensure continuity of critical activities."

<u>NEJM</u>: False Negative Tests for SARS-CoV-2 Infection — Challenges and Implications (05 June 2020).

"If SARS-CoV-2 diagnostic tests were perfect, a positive test would mean that someone carries the virus and a negative test that they do not. With imperfect tests, a negative result means only that a person is less likely to be infected. To calculate how likely, one can use Bayes' theorem, which incorporates information about both the person and the accuracy of the test (recently reviewed5). For a negative test, there are two key inputs: pretest probability — an estimate, before testing, of the person's chance of being infected — and test sensitivity. Pretest probability might depend on local Covid-19 prevalence, SARS-CoV-2 exposure history, and symptoms. Ideally, clinical sensitivity and specificity of each test would be measured in various clinically relevant real-life situations (e.g., varied specimen sources, timing, and illness severity)."

<u>Sci Immunol</u>: Inhibition of Bruton tyrosine kinase in patients with severe COVID-19 (05 June 2020)

"Patients with severe COVID-19 have a hyperinflammatory immune response suggestive of macrophage activation. Bruton tyrosine kinase (BTK) regulates macrophage signaling and activation. Acalabrutinib, a selective BTK inhibitor, was administered off-label to 19 patients hospitalized with severe COVID-19 (11 on supplemental oxygen; 8 on mechanical ventilation), 18 of whom had increasing oxygen requirements at baseline. Over a 10-14 day treatment course, acalabrutinib improved oxygenation in a majority of patients, often within 1-3 days, and had no discernable toxicity. Measures of inflammation — C-reactive protein and IL-6 — normalized quickly in most patients, as did lymphopenia, in correlation with improved oxygenation. At the end of acalabrutinib treatment, 8/11 (72.7%) patients in the supplemental oxygen cohort had been discharged on room air, and 4/8 (50%) patients in the mechanical ventilation cohort had been successfully extubated, with 2/8 (25%) discharged on room air. Ex vivo analysis revealed significantly elevated BTK activity, as evidenced by autophosphorylation, and increased IL-6 production in blood monocytes from patients with severe COVID-19 compared with blood monocytes from healthy volunteers. These results suggest that targeting excessive host inflammation with a BTK inhibitor is a

therapeutic strategy in severe COVID-19 and has led to a confirmatory international prospective randomized controlled clinical trial."

<u>Circulation</u>: Prevalence of COVID-19 in Out-of-Hospital Cardiac Arrest: Implications for Bystander CPR (04 June 2020)

"We undertook a cohort investigation of OHCA [out-of-hospital cardiac arrest] attended by emergency medical services (EMS) in Seattle and King County, WA from January 1 to April 15, 2020. Patients where EMS attempted resuscitation (EMS treated) and where EMS responded but did not provide resuscitation because of signs of irreversible death (dead on EMS arrival) were included....

As of April 15, our community had 15 deaths per 100,000 population from COVID-19, higher than 42 other states at that time. COVID-19 was diagnosed in less than 10% of OHCA. Assuming the risk of transmission to bystanders performing hands-only CPR without PPE is 10%, treating 100 patients could result in 1 bystander infection (10% with COVID-19 x 10% transmission). Given a 1% mortality for COVID-19, approximately 1 rescuer might die in 10,000 bystander CPR events. By comparison, bystander CPR saves more than 300 additional lives among 10,000 patients with OHCA. We believe the current findings support telecommunicators and bystanders maintaining the most efficient approach that prioritizes rapid identification of cardiac arrest and immediately proceeds to chest compressions and use of a defibrillator. Delaying bystander CPR to implement PPE should only be considered when the prevalence of COVID-19 is substantially increased."

<u>Eurosurveill</u>: SARS-CoV-2-related paediatric inflammatory multisystem syndrome, an epidemiological study, France, 1 March to 17 May 2020 (04 June 2020)

"This study is, to date, the largest series of published PIMS [paediatric inflammatory multisystem syndrome, or multisystem inflammatory syndrome in children (MIS-C)] cases, with more than 100 cases. It supports a causal relationship between SARS-CoV-2 infection and PIMS: 95 of the 156 notified cases were confirmed or probable post-COVID cases. Among the 48 excluded cases, 39 presented with KLD symptoms, probably reflecting the classical Kawasaki disease. Our case definition differed slightly from those proposed later on by the WHO, the RCPCH and the US CDC, mainly because we included as a possible case a patient with a pending or not performed diagnosis of SARS-CoV-2 infections. However, we believe that having classified them as possible PIMS cases reflects the actual likelihood of those cases being real PMS cases. Moreover, possible cases only represented 12% of all cases kept in the analysis and their temporal distribution as well as their age distribution and clinical features (data not shown) did not differ from those of probable and confirmed cases. The significant differences between the CoV2-PIMS and non-CoV2 PIMS cases regarding age distribution and main manifestation support a correct classification. We also highlight that further clinical reporting on all manifestations is required to improve the case definition and disease description."

<u>Neurology</u>: Neurologic manifestations in hospitalized patients with COVID-19: The ALBACOVID registry (01 June 2020)

"We systematically review all patients diagnosed with COVID-19 admitted to hospital in a Spanish population during March 2020. Demographic characteristics, systemic and neurological clinical manifestations, and complementary tests were analyzed....

To our knowledge, this work comprises the largest hospital-based cohort of COVID-19 patients to date in which neurological symptoms were systematically analyzed. More than a half of patients with COVID-19 (57.4%) developed at least one neurological symptom, a proportion significantly higher than the 36.4% reported in previous studies."

Webinars

WHO: American Public Health Association (APHA) and the National Academy of

Medicine (NAM)

WHAT: Responding to COVID-19: A Science-Based Approach webinar series

#9: The Road to Immunity During COVID-19 — Developing and Distributing a

Vaccine

WHEN: 10 June (Wednesday) 1700-1830 ET

HOW: Register at: https://www.covid19conversations.org/webinar-registration

Past webinars in this series are recorded and available for continuing education credits. Topics include: the science of social distancing; crisis standards of care; testing; health equity and disparities; protecting public health; and mitigation efforts. For more information, see: https://www.covid19conversations.org/

WHO: American Medical Association (AMA) Journal of Ethics

WHAT: Ethics Talk: Spread of Anti-Asian Racism and Xenophobia During COVID-19

Pandemic

"In this video edition of Ethics Talk, journal editor in chief, Dr Audiey Kao, talks with Dr Jennifer Ho about understanding and combatting the spread of anti-Asian racism and xenophobia during this COVID-19 pandemic."

Available on demand at: https://journalofethics.ama-assn.org/podcast/ethics-talk-spread-anti-asian-racism-and-xenophobia-during-covid-19-pandemic

For other Ethics Talk videos and resources, see: https://journalofethics.ama-assn.org/covid-19-ethics-resource-center

See also the AMA COVID-19 resource center for news, virtual events, and other discussions at: https://www.ama-assn.org/delivering-care/public-health/covid-19-2019-novel-coronavirus-resource-center-physicians

In Brief

After reviewing 20 national forecasts, the CDC predicts between 118,000 and 143,000 cumulative COVID-19 deaths by June 27 (CDC).

According to two new studies (<u>Nature</u> [#1]; <u>Nature</u> [#2]), shutdown orders prevented about 60 million coronavirus infections in the US and saved about 3.1 million lives in Europe (<u>WashPo</u>).

New Zealand has "officially eradicated COVID-19" (at least for now) after the last known case has recovered and will reset to the lowest alert level, lifting all restrictions on gatherings and returning to normal operations (NPR).

Stay Safe Out There

The WHO has updated guidance to say everyone should wear cloth masks in public (WHO).

Wearing masks all the time may impact how we interact with each other (Vox).

Navigating public spaces, including elevators, in a safe way and managing risk can be tricky in the age of COVID-19 (NPR).

When will it be safe to do everyday things again? Well, it depends (NYT).

Vaccines, Treatments, and Recovery

Two US Representatives have introduced legislation to ensure mass production and administration of a COVID-19 when available (HPN).

The current supply of remdesivir will run out at the end of June, according to a US Department of Health and Human Services official (CNN).

Some patients with COVID-19 who come off a ventilator are taking days and even weeks to wake up (WashPo).

COVID-19 patients have endured relentless waves of debilitating symptoms—and disbelief from doctors and friends (<u>Atlantic</u>).

An Army top medical research officer says they aim to have a vaccine by the end of the year, with human testing beginning in late summer (DOD).

Testing and Contact Tracing

"Positive COVID-19 tests kept a mom and baby apart for 55 days. Experts see it as a bigger testing problem" (STAT).

Smartphone apps are expected to play a major role in contact tracing COVID-19 exposure and cases (Wired).

At least half of Singapore's new cases of coronavirus show no symptoms (Reuters).

A sample survey of 9,965 residents of Bergamo, Italy found 57% had antibodies indicating exposure to the coronavirus (<u>Reuters</u>).

Army and Navy have teamed up to 3D print nasopharyngeal test swabs for COVID-19 diagnostic tests (Global Biodefense).

Disparities

For tens of millions of Americans without smartphones or speedy internet connections, the shift to telemedicine is exacerbating preexisting disparities in access to care (Wired).

Military

The DOD has contracted with Hollingsworth & Vose to increase domestic ventilator and respirator production; the \$2.2 million contract involves producing 27.5 million N95 filters, and 3.1 million N95 respirators per monthly, beginning in August (HPN).

The Air Force has developed a Portable Biocontainment Care Module (PBCM): "This self-contained, [Department of State]-owned pod, developed in partnership with MRIGlobal, is specifically designed to protect crews and aircraft from follow-on contamination resulting from the transport of people exposed to infectious diseases, including COVID-19" (Global Biodefense).

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Statistics

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Pediatric Inflammatory Multisystem Syndrome

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Hydroxychloroquine (HCQ) in COVID-19

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Selected Primary Literature

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